Oregon
Theodore R. Kulongoski, Governor

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Environmental Public Health
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April 28, 2010

The Honorable Edward J. Markey, Chairman
Subcommittee on Energy and Environment
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Markey:

In response to your March 18, 2010 letter, Oregon's Office of Environmental Public Health, Radiation Protection Services section has researched appropriate information for the 15 questions posed regarding oversight of patients with radioisotopes related to 10 CFR 35.75 radioisotope therapy regulations. For greatest clarity, responses are keyed to each individual question.

Question 1: How many I-131 licensee facilities are overseen by your State?
Response: 24. *{Oregon Licensee listing attached}*

Question 2: How often does your State perform sampling inspections for each of these I-131 licensee facilities?
Response: Oregon inspects these licensees at least every three years
(Note: NRC Program Code 02201 is assigned a 5 year frequency in MC 2800 guidance)

Question 3: What does such an inspection entail?
Response: An inspection generally consists of:

- **Pre-visit license inspection or preparation and review of licensee incident history**
- **On-site evaluation based on Nuclear Regulatory Commission's (NRC), Inspection Procedures IP87130 through IP87133, as appropriate**
- **On-site observations, interviews, document review and demonstrations of radioisotope handling, administration and patient discharge procedures**
- **Review of selected medical cases**
- **Review of training of workers and patients to include written instructions**

Related Oregon RPS inspection documents are attached:

- *RPS Standard Operating Procedure MedRam 2010.2*
- *MedRAM 2010 guide Revision 14. 2010*

Question 4: NCRP 155 includes radiation safety guidance for I-131 therapy. What instructions has your State given to its medical licensees about how to provide guidance to patients to ensure that these radiation precautions will be followed?
Response: State administrative rules do not address all possible medical therapy scenarios. The responsibility to properly advise and treat therapy patients lies with the medical facility within the practice of medicine. In order to clarify rule requirements, Oregon refers licensees to U.S. Nuclear Regulatory Commission NUREG 1556 (Volume 9) for licensing guidance of these facilities and related Informational Bulletins or Regulatory Issue Summaries.

Question 5: In the past ten years, how many times has your State, as part of the inspections it conducts, requested documentation from the licensee facilities that details the individualized analysis and/or dose calculations used when determining whether to send a patient that was treated with I-131 in excess of the default values home, or to a hotel?
Response: Patient release policies, practices and documentation are part of the focus elements reviewed during inspection of all medical therapy licensees. Approximately 70 medical therapy licensee inspections have been conducted in the past ten years.

Question 6: In the past ten years, how many times has your State, as part of the inspections, requested documentation from the licensee facilities that details the guidance provided to the patient by the licensee facility when the patient is released from licensee care?
Response: A representative sampling of documents and records regarding patient releases are reviewed every inspection. To protect patient confidentiality under HIPAA requirements, copies of patient records reviewed are not made part of the inspection file. Guidance documents are not retained after review at the licensed facilities, unless an issue is noted with the advice provided to patients. We have not cited any Oregon medical licensees for violation of the equivalent state rule (OAR 333-116-0260) to 10 CFR 35.75 regarding I-131 therapy patient release.

Question 7: In the past ten years, how many times has your State identified problems with the individualized analysis and/or dose calculations used or guidance provided to the patient by the licensee facility?
Response: In the past ten years, Oregon has not identified compliance issues with the individualized analysis and/or dose calculations used or guidance provided to the patient by medical therapy licensees for I-131 therapy.

Question 8: In a situation where an individualized analysis of dose to others is required, it would seem impossible for the authorizing physician to do so for a patient going to a hotel, since this would require knowledge of the layout of the hotel and the proximity to the nearest other guest, who might be a child or a pregnant woman sleeping on the other side of the wall. Do you agree?
Response: Interviews with physicians indicate that the Authorized User will not authorize any administration for which they cannot perform a dose calculation. Oregon hospitals use simplified conservative thresholds to ensure that dose limits are not approached. Physicians will not allow a patient to be released unless the patient is discharged to a single family structure or under nursing care.

Question 9: Has your State ever attempted to determine how many times patients treated with I-131 are a) sent home, b) sent to a hotel or c) kept in the hospital for additional time? If so, please provide the results. If not, why not?
Response: Oregon has not performed any surveys or statistical analysis to determine the number of releases to homes or public facilities. Such work has not been performed because the focus of the medical therapy inspection program is on safety to all members of the public regardless of the patient's discharge destination. We periodically receive inquiries about radioisotope therapy from medical facilities, patients or the general public and our technical staff both provide pertinent information in response and refer patients to their medical treatment provider for specific guidance.

Question 10: In patients with doses in excess of the default limits, has your State ever attempted to determine whether these I-131 licensee facilities always perform individualized analysis of each patient's living circumstances prior to releasing them? If not, why not?
Response: Yes. Oregon evaluates patient release limits during each inspection. Several of the Oregon hospitals contract with health physics consultants to evaluate medical procedures for compliance with dose limits and provide guidance to maintain compliance.

Question 11: What are the disclosure rules for patients who go to a hotel following treatment? Are licensees required to give patients explicit instructions to provide to hotel management?
Response: Oregon has no specific disclosure rules for patient release criteria. Oregon's rule on patient release is written to comply with compatibility requirements of the U.S. Nuclear Regulatory Commission regulations in 10 CFR 35.75.

Question 12: Has your State ever issued an advisory or guidance warning licensees not to send radioactive patients to hotels? If so, please provide copies.
Response: Yes. See attached memo, *Supplemental guidance for patient release after therapeutic administration of Iodine-131.*

Question 13: Are your licensees required to report to you instances in which released I-131 patients caused radiation exposure to family members or members of the public?
Response: Medical therapy licensees are committed to the model procedures in NUREG 1556 Volume 9 for evaluating each patient's living circumstances in relation to their therapy treatment to ensure that the levels of exposure to family members or members of the public are within regulatory limits as part of their license application and the references in the final license condition which requires their adherence to these procedures or they need to provide equivalent procedures in their license application. If licensees discover that instructions were not followed or limits were exceeded, they are required to report this information under the provisions of Oregon Administrative Rules (OAR) 333-120-0710 as an incident requiring investigation by the State.
{OAR Weblink: http://arcweb.sos.state.or.us/rules/OARs_300/OAR_333/333_120.html}

Question 14: Please provide copies of all correspondence, including emails, letters, meeting or telephone notes or other materials between your State and the NRC related to the release of patients that have been treated with radio-nuclides.

Response: Oregon follows the NRC NUREG guidance 1556, volume 9, revision 2, NCRP 94 and ICRP 103. Our files review did not identify any specific correspondence between Oregon and the NRC directly relating to this subject.

Question 15: Please also provide reports for instances in which documents relating to patient release were found to be missing, inadequate, or unclear during the course of a sampling inspection. If your sampling inspections found that a licensee knew of a patient who went to a hotel after treatment, whether or not by explicit instruction, please provide all documentation relating to those cases.
Response: A search of our inspection files has not revealed any instances responsive to this question.

Thank you for your championship of radiation safety. If you need clarification or additional information related to this correspondence, please contact me at 971-673-0499 or by email at: terry.d.lindsey@state.or.us

Sincerely,

Terry D. Lindsey
Section Manager
Radiation Protection Services

RMLICN	RMLICENSEE	RMTYPE	Text37	Text49	Text51
90158	Portland Adventist Medical Center	Medical Diagnostic/Therapy QMP	Portland	BilyeuMN@ah.org	(503) 251-6305
90248	Providence Health & Services-Oregon	Radiopharmaceutical Therapy	Medford	joe.hellman@providence.org	(541) 732-7019
90270	Sacred Heart Medical Center	Radiopharmaceutical Therapy	Springfield	mbf@rapc.com	(541) 686-7010
90283	Tuality Community Hospital	Radiopharmaceutical Therapy	Hillsboro	shakuntala.krishnamurthy@tuality.org	(503) 681-1091
90293	Legacy Meridian Park Medical Center	Radiopharmaceutical Therapy	Tualatin	blanders@lhs.org	(503) 692-2593
90294	Providence Willamette Falls Medical Center	Radiopharmaceutical Therapy	Oregon City	marlene.tynan@wfhonline.org	(503) 657-6943
90151	Salem Hospital	Radiopharmaceutical Therapy	Salem	marjorie.slauson@salemhospital.org	(503) 561-5568
90321	Mid-Columbia Medical Center	Radiopharmaceutical Therapy	The Dalles		(541) 296-7251
90442	Sky Lakes Medical Center, Inc.	Radiopharmaceutical Therapy	Klamath Falls	WMilimuka@skylakes.org	(541) 274-4551
90464	Kaiser NW Permanente	Radiopharmaceutical Therapy	Clackamas		(503) 571-4970
90510	Cascade Health Services, Inc.	Radiopharmaceutical Therapy	Redmond	chammond@cascadehealthcare.org	(541) 706-7724
90373	Mercy Medical Center, Inc.	Radiopharmaceutical Therapy	Roseburg	stevenlane@chiwest.com	(541) 677-2390
90565	Northwest Medical Foundation of Tillamook dba	Radiopharmaceutical Therapy (OAR 333-116-360)	Tillamook	gordonGJ@ti1.ah.org	
90962	Northwest Cancer Specialists	Radiopharmaceutical Therapy (OAR 333-116-360)	Portland	Stephen.Gibb@USOncology.com	(503) 280-1223
90974	The Corvallis Clinic, P.C.	Radiopharmaceutical Therapy (OAR 333-116-360)	Corvallis	ronald.mccrae@corvallis-clinic.com	
91080	Samaritan Albany General Hospital	Radiopharmaceutical Therapy (OAR 333-116-360)	Albany	csulliva@samhealth.org	(541) 812-5411
90343	Columbia Memorial Hospital	Radiopharmaceutical Therapy (OAR 333-116-360)	Astoria	nmcsi@proaxis.com	(503) 338-7525
90990	Samaritan Lebanon Community Hospital	Radiopharmaceutical Therapy (OAR 333-116-360)	Lebanon	pmuna@samhealth.org	(541) 451-7192
90312	Providence Health & Services-Oregon	Radiopharmaceutical Therapy (OAR 333-116-360)	Milwaukie	ronald.larson@providence.org	(503) 513-8350
90317	Three Rivers Community Hospital	Radiopharmaceutical Therapy (OAR 333-116-360)	Grants Pass	jprive@asante.org	(541) 472-7151
90181	Legacy Mt. Hood Medical Center	Radiopharmaceutical Therapy (OAR 333-116-360)	Tualatin	blanders@lhs.org	(503) 692-2593
90202	Good Samaritan Regional Medical Center	Radiopharmaceutical Therapy (OAR 333-116-360)	Corvallis	eshiner@samhealth.org	(541) 768-5220
90243	Cascade Healthcare Community, Inc.	Radiopharmaceutical Therapy (OAR 333-116-360)	Bend	chammond@cascadehealthcare.org	(541) 706-7724
90422	Community Cancer Center	Therapy-Pivate/QMP Required	Roseburg	physics@cccroseburg.org	(541) 673-2267

RPS STANDARD OPERATING PROCEDURE

Procedure Name: MedRAM 2010.2	No. 011

Approved by: _____
RPS Section Manager

_____
Program Manager

Effective date:
Supercedes: MED 2007.3
Revised: 21 Jan 2010
Review Date: 21 Jan 2011 (1year)

Reference	Focus elements based on U.S. Nuclear Regulatory Commission (NRC) Procedures: IP87130, IP87131, IP87132, IP87133, IP87134. Additional references: Oregon Administrative Rules (OARs) 333-100 to 124 which cover radioactive material (RAM) use, Titles 10, 40, 49 Code of Federal Regulations, NUREG 1556 Vol 9 Rev 2, SA-300, National Council on Radiation Protection and Measurements (NCRP) several titles, MedRAM 2010.2 Guide.
Attachments	Procedure and Form MedRAM 2010.2
Objective	Update medical RAM inspection procedures, and expand traditional focus elements. The new procedure is in the form of a checklist. The checklist format should help managers and auditors understand the scope of medical inspections.
Guidelines	Inspections ▪ Inspections are generally unannounced ▪ To be completed in an efficient manner ▪ Be flexible for unannounced inspections ▪ Follow Inspection Preparation Protocol
Equipment Required	1. Procedure/checklist MedRAM 2010.2 2. Pertinent OARs 3. Oregon Form 591 + Cover Letter 4. Radiation detection equipment and sample media appropriate to the licensee's RAM use 5. Personal Protective Equipment appropriate to the facility
Procedure	Procedure MedRAM 2010.2 is attached to this cover page. Standard RAM inspection protocols apply to all medical RAM inspections.
Suggested Enhancements	Entries on the first two pages of the inspection report reflect information found in the database. Ideally this information would be auto-filled, from the database.

INSPECTION, LICENSING, AND INCIDENT HISTORY

The inspector should review the licensee's inspection, licensing, and incident history prior to inspection. The inspector should record pertinent details from this pre-inspection review on this page. This page also includes follow-up questions to relate inspection preparation to inspection findings.

Items of Noncompliance were identified during any of the last two inspections or two years, whichever is longer (N/A = Initial inspection) ☐N/A ☐Y ☐N

NM: Form 591 dated: _____C. Licensee response letter dated: _____ D. Closed Loop letter dated:_____
Items of Noncompliance from previous inspection(s):

Requirement Cited	Specific Issue	Severity Level	Status

License amendments issued since last inspection, or program changes noted in the license:

Amendment	Date	Subject

Was the licensee compliant with licensing and inspection changes listed above? ☐N/A ☐Y ☐N

Incident Review:

List any incidents or events reported since the last inspection ☐None

Personnel Contacted:
Record licensee, or pertinent 3rd party personnel contacted during the inspection. This should include members of management, the RSO, Authorized Users (AUs), supervised personnel, and consultants.

FE1 Security and Control of Licensed Material
The inspector should independently verify the licensee controls access to RAM and radiation.

Sat N/A NR Rec INC

☐ ☐ ☐ ☐ ☐ Facilities
- Locations of use must be licensed OAR 333-116-0040
- Facilities/Procedures outside the Radiology Dept
- Materials and forms match license

☐ ☐ ☐ ☐ ☐ RAM must be physically secured or under surveillance
- RAM in storage OAR 333-120-0250
- RAM not in storage OAR 333-120-0260
- HDR and Gamma Knife extra requirements OAR 333-116-0495

☐ ☐ ☐ ☐ ☐ RAM Use per license and OARs
- Authorized Users
  - Visiting Authorized User up to 60 Days OAR 333-116-0110
- Authorized Medical Physicists
- Authorized Radiopharmacists
- Supervised use OAR 333-116-0100, OAR 333-100-0005

☐ ☐ ☐ ☐ ☐ Special Access Controls and Postings
(See MedRAM2010 Guide FE6)

☐ ☐ ☐ ☐ ☐ Inventory Control (See MedRAM2010 Guide FE1)
- Inventories
- Leak Tests
- Disposal OAR 333-120-0500

☐ ☐ ☐ ☐ ☐ Effluent Release
- Aerosols and Gases controlled per OAR 333-116-0340
- Public Dose **Restriction**: 100 mrem/year OAR 333-120-0180
- References values in 10 CFR 20 Appendix B
- Sanitary Sewer Release per OAR 333-120-0520 tied to 10 CFR 20 Appendix B Table 3
- Public Dose **Constraint:** 10 mrem/year OAR 333-120-0020(4)
  - Equivalent of 10 CFR 20.1101(d)
  - If exceeded, licensee notifies RPS within 30 days per OAR 333-120-0720

☐ ☐ ☐ ☐ ☐ Receipt and Transfer
- Compliance with federal rules is mandatory OAR 333-118-0050(1)(a)
- Records for receipt, transfer, and disposal of all radiation sources OAR 333-100-0055
- Compliance with federal rules is mandatory OAR 333-118-0050(1)(a)
  - 49 CFR 107, 171-180, and 390-397
- Packages are compliant
- Accounting/Tracking system appropriate

FE3 Comprehensive Safety Measures

The inspector should independently verify the licensee has implemented comprehensive safety measures to limit non-radiological hazards to worker and the public.\

Sat N/A NR Rec INC

☐ ☐ ☐ ☐ ☐ Non-Radiological safety issues

- Culture of Safety in place (Federal Register Volume 74, No. 214, Friday November 6, 2009)
- OR-OSHA concerns
  - RPS must notify OR-OSHA, if issues identified
- Board of Pharmacy
  - E.g. compliance with USP 797
- Accreditation
  - ACR
  - ICANL
- Camera QC per manufacturer's instructions OAR 333-116-0550
- Elution Test "Moly Break-Through" below 0.15 uCi/mCi OAR 333-116-0330

Comments on FE3 Findings:

FE4 Radiation Dosimetry Program

The inspector should independently verify the licensee has implemented an appropriate dosimetry program. The dosimetry program must accurately assess radiation dose, from the licensee's activities, to workers, and members of the public.

Sat N/A NR Rec INC

☐ ☐ ☐ ☐ ☐ ALARA Program developed and implemented

☐ ☐ ☐ ☐ ☐ Dose Restrictions

Dose Restriction Table					
Category	DDE (rem)	SDE (rem) 7 mg/cm^2	LDE (rem) 300 mg/cm^2	TEDE (rem)	Reference
Worker	5	50	15	5	OAR 333-120-0100
Minor Worker	0.5	5	1.5	0.5	OAR 333-120-0160
Worker's Embryo/Fetus				0.5	OAR 333-120-0170
Public Member				0.1	OAR 333-120-0180(1)(a)
Patient Visitor				0.5	OAR 333-120-0180(3) *If approved by AU
Unrestricted Area	0.05				OAR 333-120-0190(2)(b)(B)

☐ ☐ ☐ ☐ ☐ Worker Dose OAR 333-120-0210

- External monitoring

- Emergency Response Instruments
  - Includes RPS HPP/REP instruments

INSPECTOR's Survey Instruments: Record information on inspector instruments

Manufacturer	Model #	Serial Number	Calibration Dates	Notes

Licensee Instruments: Record information on Licensee instruments observed during inspection.

Manufacturer	Model #	Serial Number	Calibration Dates	Notes

Dose Calibration Devices: Record Dose Calibrator information.

DOSE CALIBRATOR		QUARTERLY LINERARTY 116-0160(2)(c)	1ST QTR	2ND QTR	3RD QTR	4TH QTR
MANUFACTURER						
MODEL						
SERIAL NUMBER						
GEOMETRY 116-0160(2)(d)						
ACCURACY 116-0160(2)(b)						

Comments on FE5 Findings:

FE6 Radiation Safety Training and Practices

The inspector should independently verify the licensee workers have an adequate level of radiation protection knowledge, and operational ability. The radiation safety training program must ensure safe work in normal, and accident conditions.

Sat N/A NR Rec INC

☐ ☐ ☐ ☐ ☐ Assess training program, implementation and effectiveness
- Observations, demonstrations, interviews, document review
- Refer to training requirement table in SOP Reference
- Postings, Notices, and posted instructions (See MedRAM2010 Guide FE6)

☐ ☐ ☐ ☐ ☐ RSO Training

☐ ☐ ☐ ☐ ☐ AU Training

☐ ☐ ☐ ☐ ☐ AMP Training

☐ ☐ ☐ ☐ ☐ Supervised Worker Training

☐ ☐ ☐ ☐ ☐ Ancillary Worker Training

FE1 Security and Control of Licensed Material

- Facilities
  - Locations of use must be licensed OAR 333-116-0040
    - Restricted Area: access restricted to protect from radiation OAR 333-120-0015(69)
    - Controlled Area: outside Restricted Area, yet within site boundaries OAR 333-120-0015(17)
      - Specific limitations may be placed
      - Public Dose limits in effect OAR 333-120-0180(2)
    - Unrestricted Area
      - Not limited or controlled OAR 333-120-0015(80)
      - Dose Rate restricted to 2 mrem/hr OAR 333-120-0190(2)(b)(B)
      - Dose restricted to 50 rem/year (not 100 rem)
  - Facilities/Procedures outside the Radiology Dept
    - Fluoroscopy Procedures with RAM-use
    - Sentinal Node
    - Emergency Room/Dept
    - Mammography
    - Additional guidance: NCRP 133
  - Materials and forms match license
- RAM must be physically secured or under surveillance
  - RAM in storage OAR 333-120-0250
  - RAM not in storage OAR 333-120-0260
  - HDR and Gamma Knife extra requirements OAR 333-116-0495
    - Secure unit
    - Secure Console
    - Secure Keys
    - Secure Treatment room
    - Personnel present must be approved (by AU, AMP, RSO)
- RAM Use per license and OARs
  - Authorized Users
    - Visiting Authorized User up to 60 Days OAR 333-116-0110
      - Management and RSC written permission
      - Visiting physician is an AU on another license
  - Authorized Medical Physicists
  - Authorized Radiopharmacists
  - Supervised use OAR 333-116-0030, 0100, OAR 333-100-0005
- Special Access Controls and Postings (see table in FE6 Radiation Safety Training and Practices)
- Inventory Control (See Inv/LT requirements table at end of FE1)
  - Inventories
  - Leak Tests
    - 5-day report requirement to RPS if a source is Leaking 333-120-0720(1)(e)
    - Remove leaking source from Service 333-120-0460(6)
    - Prevent spread of contamination 333-120-0460(6)
  - Disposal OAR 333-120-0500
    - Transfer of Waste and Waste Alarms
    - Decay in Storage OAR 333-102-0305(23), OAR 333-116-0290
      - $T_{1/2} < 65$ days
      - I-125 in uCi amounts decays for 5 $T_{1/2}$
      - All other decay for 10 $T_{1/2}$
      - Remove Radiation labels prior to release
      - Survey at package surface prior release
      - (NRC 10 CFR 35.92 is less restrictive)
        - $T_{1/2} < 120$ days
        - No time for decay listed
        - See NRC Regulatory Issue Summary (RIS) 2004-17

Package Survey						
Contaminant	**Package Limits** 300 cm^2 Surface ~1/2 sheet printer paper 333-118-0150 table 3		**Real World Measurements**		**Dose Rate** 333-118-0150(11)	
	uCi/cm^2	dpm/cm^2	Total Limit on a 300 cm^2 DOT wipe	NOTE: Most facilities use 100 cm^2 normalized to 300 cm^2 so limit is	External surface	Closed Transport Vehicle
Beta Emitters	1E-5	22	6600 dpm	2200 dpm	200 mrem/hr	1000 mrem/hr
$T_{1/2} < 10$ days	1E-5	22	6600 dpm	2200 dpm		
Ores or Physical Concentrates: Natural Uranium, Natural Thorium U-235, U-238, Th-232, Th-228, Th-230	1E-5	22	6600 dpm	2200 dpm		
All other Alpha Emitters	1E-6	2.2	660 dpm	220 dpm		

Leak Test Requirements				
Contaminant or Survey Type	**Leak Tests** Tested over 100 cm^2 Surface ~size of dollar bill, compact disc, or two driver's licenses		Reference	Additional Requirements
	Test Frequency	Test Limit		
Beta or Gamma > 100 uCi	6 months or if damaged	185 Bq (0.005 uCi)	120-0460	
Alpha > 10 uCi	3 months or if damaged	185 Bq (0.005 uCi)	120-0460	
Ra-226 Brachytherapy Source	3 months or if damaged	185 Bq (0.005 uCi)	116-0200 333-120-0460	
		37 Bq (0.001 uCi) of radon-222 in 24 hours	116-0200 120-0460	
Brachytherapy Sources (not Ra-226)	6 months Per 333-116-0200	185 Bq (0.005 uCi)	116-0200 116-0450 120-0460	Confirm No sources missing
$T_{1/2} < 30$ days		No Leak Test	120-0460	

FE4 **Radiation Dosimetry Program**

- ALARA Program developed and implemented
- Dose Restrictions

Dose Restriction Table					
Category	DDE (rem)	SDE (rem) 7 mg/cm^2	LDE (rem) 300 mg/cm^2	TEDE (rem)	Reference
Worker	5	50	15	5	OAR 333-120-0100
Minor Worker	0.5	5	1.5	0.5	OAR 333-120-0160
Worker's Embryo/Fetus				0.5	OAR 333-120-0170
Public Member				0.1	OAR 333-120-0180(1)(a)
Patient Visitor				0.5	OAR 333-120-0180(3) *If approved by AU
Unrestricted Area	0.05				OAR 333-120-0190(2)(b)(B)

- Worker Dose OAR 333-120-0210
  - External monitoring
  - Bioassay OAR 333-120-0130
    - Within 3 days (if prepared or administered I-131) OAR 333-116-0380(1)(h)
  - ALI and DAC calculations OAR 333-120-0130
  - Declared Pregnant and Embry/Fetus program OAR 333-120-0170
    - Woman may not be coerced into declaration
    - Must declare in writing
    - Must be monitored if expected to receive > 0.1 rem DDE
  - PPE and respiratory protection
  - Dose reported to workers OAR 333-111-0015
  - Overexposures OAR 333-120-0720
    - Licensee may set Internal ALARA Limits
  - Planned Special Exposures OAR 333-120-0150
    - May not exceed all occupational dose limits **and** 5 times the annual limit during their lifetime
    - Must be reported to RPS
- Public and Ancillary Worker Dose OAR 333-120-0180, 0190
  - Dose Limits and Exposure Rate Limits not exceeded
    - Visitors should be >18 years old, or approved by AU OAR 333-116-0380(1)(c)
    - AU may request RPS pre-approval for 500 mrem dose to a public member OAR 333-120-0180(4)
    - Visitor Dose may be pre-approved up to 500 mrem EDE (NRC RIS 05-24)
      - May estimate EDE with surveys (see Health Physics Vol 89, No 3)
  - Area monitoring (See FE5)
  - Effluents Limits (See FE1)
  - Effluent Constraints (See FE1)
  - Engineering controls
  - Surveys, contamination tests, effluent calculations (See FE1 and FE5)
  - Waste (See FE1)
  - Bio-waste monitored and controlled (See FE1 and FE5)
    - Stericycle of Morton, WA services most OR licensees
    - Acceptance criteria for waste facilities more Strict than OARs

- Collimator size
- Plug pattern
- Total dose
- Total treatment volume for each treatment site

- Teletherapy
  - Total dose
  - Dose per fraction
  - Number of fractions
  - Treatment site
  - Overall treatment period
- Afterloaders
  - Radionuclide
  - Treatment site
  - Dose per fraction
  - Number of fractions
  - Total dose
- Other Brachytherapy
  - Prior to implant
    - Treatment site
    - Radionuclide
    - Number of sources
    - Source strengths (each source) OR dose
  - After implant, prior to completion additions:
    - Total source strength
    - Exposure time OR total dose

- Patient Release (Outpatients with radiopharmaceuticals or permanent implants) 333-116-0260 (10 CFR 35.75)
  - Permitted if:
    - TEDE to member of Public less than 0.5 rem
      - Annual dose, not per treatment (NRC RIS-08-07)
    - Patient/subject or guardian is provided written instructions
      - ALARA recommendations if public dose may exceed 0.1 rem (1 mSv)
      - If dose to breastfeeding child could exceed 0.1 rem (1 mSv):
        - Guidance on interruption or discontinuation of breast feeding
        - Biological effects/consequences if guidance is not followed
      - Record must maintain the basis for release
    - Additional Guidance
      - I-131 ~~Dose to Children~~: Internal > TEDE (NRC RIS-08-11, ICRP 94, ICRP 103)
        - ~~More conservative~~ approach is needed for patients with access to children
      - Caregivers (e.g. family-member caring for patient) may receive higher doses
        - Licensee must pre-arrange Exemption (NRC RIS 06-18)
        - NRC suggests a 2 rem annual limit for caregivers
  - Policies should (not specifically required) prevent waste stream problems
    - Only required to keep public dose within limits
    - ~~E.g. portal monitors~~
- Misadministrations (See Reportable Medical Incidents Table in FE4)
- Medical Events (See Reportable Medical Incidents Table in FE4)

FE4 **Radiation Dosimetry Program**

- ALARA Program developed and implemented
- Dose Restrictions

Dose Restriction Table					
Category	DDE (rem)	SDE (rem) 7 mg/cm^2	LDE (rem) 300 mg/cm^2	TEDE (rem)	Reference
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Minor Worker	0.5	5	1.5	0.5	OAR 333-120-0160
Worker's Embryo/Fetus				0.5	OAR 333-120-0170
Public Member				0.1	OAR 333-120-0180(1)(a)
Patient Visitor				0.5	OAR 333-120-0180(3) *If approved by AU
Unrestricted Area	0.05				OAR 333-120-0190(2)(b)(B)

- Worker Dose OAR 333-120-0210
  - External monitoring
  - Bioassay OAR 333-120-0130
    - Within 3 days (if prepared or administered I-131) OAR 333-116-0380(1)(h)
  - ALI and DAC calculations OAR 333-120-0130
  - Declared Pregnant and Embry/Fetus program OAR 333-120-0170
    - Woman may not be coerced into declaration
    - Must declare in writing
    - Must be monitored if expected to receive > 0.1 rem DDE
  - PPE and respiratory protection
  - Dose reported to workers OAR 333-111-0015
  - Overexposures OAR 333-120-0720
    - Licensee may set Internal ALARA Limits
  - Planned Special Exposures OAR 333-120-0150
    - May not exceed all occupational dose limits **and** 5 times the annual limit during their lifetime
    - Must be reported to RPS
- Public and Ancillary Worker Dose OAR 333-120-0180, 0190
  - Dose Limits and Exposure Rate Limits not exceeded
    - Visitors should be >18 years old, or approved by AU OAR 333-116-0380(1)(c)
    - AU may request RPS pre-approval for 500 mrem dose to a public member OAR 333-120-0180(4)
    - Visitor Dose may be pre-approved up to 500 mrem EDE (NRC RIS 05-24)
      - May estimate EDE with surveys (see Health Physics Vol 89, No 3)
  - Area monitoring (See FE5)
  - Effluents Limits (See FE1)
  - Effluent Constraints (See FE1)
  - Engineering controls
  - Surveys, contamination tests, effluent calculations (See FE1 and FE5)
  - Waste (See FE1)
  - Bio-waste monitored and controlled (See FE1 and FE5)
    - Stericycle of Morton, WA services most OR licensees
    - Acceptance criteria for waste facilities more Strict than OARs

Reportable Medical Incidents				
	Specific Category	**Reference**	**Criteria**	**Reporting Requirement**
Misadministration	**Diagnostic > 30 uCi** I-123, I-125, I-131	OAR 333-116-1010(1)(a)	• Wrong individual • wrong pharmaceutical • Administered dosage exceeds 20% prescribed dosage	Basic Requirements 333-116-0130 (records) 333-116-1010(2,3) 1) Telephone RPS by next calendar day 2) Written report to RPS within 15 days of discovery **RPS must report Therapeutic Misadmins to NRC** 15-day report to RPS 1) Licensee Name 2) Prescribing Physician 3) Description of event 4) Cause of the event 5) Effect to the patient 6) Corrective actions, or planned actions 7) Certification of patient (or guardian) notification DO NOT: Do not include the patient's name, or identification information.
	Diagnostic < 30 uCi I-123, I-125, I-131	OAR 333-116-1010(1)(b)	• Wrong individual • wrong pharmaceutical • wrong route of administration • Administered dosage exceeds 36 uCi	
	Therapeutic Radiopharm (not iodine)	OAR 333-116-1010(1)(c)	• Wrong individual • Wrong pharmaceutical • Wrong route of administration • Administered dosage exceeds 20% prescribed	
	Gamma Stereotactic Radiosurgery	OAR 333-116-1010(1)(d)	• Wrong individual • Wrong treatment site • Total administered exceeds total prescribed by >10%	
	Teletherapy	OAR 333-116-1010(1)(e)	• Wrong individual • Wrong mode of treatment • Wrong Treatment site • 3 or less fractions and total administered >10% prescribed • Total administered >20% prescribed	
	Brachy-therapy	OAR 333-116-1010(1)(f)	• Wrong individual • Wrong radioisotope • Wrong treatment site (excluding migration) • Leaking Sealed Source • 1 or more seeds not removed upon completion (for temp implants) • Administered dose >20% prescribed	
Medical Event	**Dose Off** by 5 rem EDE 50 rem to organ, tissue, or skin	OAR 333-116-1000(1)(a)	• Total dose differs by ≥ 20% • Total dosage differs by ≥20% • Total dosage falls outside prescribed range • Single Fraction differs by ≥ 50%	Basic Requirements OAR 333-116-1000(3-6) Same as Misadministration Additional Requirements a) Notify the Referring Physician within 24 hours of discovery b) Notify the patient within 24 hours. -May be done by referring physician -Notification may be cancelled due to medical opinion
	Dose Exceeds 5 rem EDE 50 rem organ, tissue, or skin	OAR 333-116-1000(1)(b)	• Wrong drug with wrong RAM • Wrong route of drug administration • Wrong individual • Wrong mode of treatment • Leaking source	
	Organ or Skin Dose >50 rem **and** ≥50% WD	OAR 333-116-1000(1)(c)	• Excludes migrated brachy seeds	
	Patient Intervention permanent damage	OAR 333-116-1000(2)	• Caused by patient intervention **and** • Unintended permanent functional damage to organ or system – determined by physician • **This is an AO under SA 300 Criteria I.A.3**	

Nuclide Specific Occupational Dose

ALI = Annual Limit on Intake

U.S. Centers for Disease Control recommends physicians consider medical counter-agents if Intake of 1 to 10 ALI

Assumes "light breathing" rate of 2E+4 ml/min

50 rem Committed Dose Equivalent (CDE)

CDE is the dose to the organ or tissue over 50 years

Organ Dose (critical organ listed)

Non-Stochastic

Or

5 rem Committed Effective Dose Equivalent (CEDE)

CEDE = ΣCDE (sum of all CDEs)

Whole body

Stochastic

If a critical organ is listed, the Stochastic Limit is listed in Parentheses( )

DAC = Derived Air Concentration

Chronic occupational exposure over a 2000 hour work-year

Inhalation or Submersion Dose

Selected Values from 10 CFR 20 Appendix B

Element	Isotope	Class	Table 1		
			Oral	Inhalation	
			ALI uCi	**ALI** uCi	**DAC** uCi/ml
55 Cesium	Cs-137	D, all compounds	1E+2	2E+2	6E-8
9 Fluorine	F-18	D, fluorides of H, Li, Na, K, Rb, Cs, and Fr	5E+4 St Wall	7E+4	3E-5
			(5E+4)	-	-
		W, fluorides of Be, Mg Ca, Sr, Ba, Ra, Al, Ga, In, Tl, As, Sb, Bi, Fe, Ru, Os, Co, Ni, Pd, Pt, Cu, Ag, Au, Zn, Cd, Hg, Sc, Y, Ti, Zr, V, Nb, Ta, Nm, Tc, and Re	-	9E+4	4E-5
		y, Lanthanum Fluoride	-	8E+4	3E-5
49 Indium	In-111	D, all Compounds except those given for W	4E+3	6E+3	3E-6
		W, oxides, hydroxides, halides, and nitrates	-	6E+3	3E-6
53 Iodine	I-123	D, all compounds	3E+3 Thyroid	6E+3 Thyroid	3E-6
			(1E+4)	(2E+4)	-
	I-125	D, all compounds	4E+1 Thyroid	6E+1 Thyroid	3E-8
			(1E+2)	(2E+2)	-
	I-131	D, all compounds	3E+1 Thyroid	5E+1	2E-8
			(9E+1)	(2E+2)	-
77 Iridium	Ir-192	D, all compounds except those given for W and Y	9E+2	3E+2	1E-7
		W, halides, nitrates, and metallic iridium	-	4E+2	2E-7
		Y, oxides and hydroxides	-	2E+2	9E-8
46 Palladium	Pd-103	D, all compounds except those given for W and Y	6E+3 LLI wall	6E+3	3E-6
			(7E+3)	-	-
		W, nitrates	-	4E+3	2E-6
		Y, oxides and hydroxides	-	4E+3	1E-6

53 Iodine	I-123	D, all compounds	-	-	-
			2E-8	1E-4	1E-3
	I-125	D, all compounds	-	-	-
			3E-10	2E-6	2E-5
	I-131	D, all compounds	-	-	-
			2E-10	1E-6	1E-5
77 Iridium	Ir-192	D, all compounds except those given for W and Y	4E-10	1E-5	1E-4
		W, halides, nitrates, and metallic iridium	6E-10	-	-
		Y, oxides and hydroxides	3E-10	-	-
46 Palladium	Pd-103	D, all compounds except those given for W and Y	9E-9	-	-
			-	1E-4	1E-3
		W, nitrates	6E-9	-	-
		Y, oxides and hydroxides	5E-9	-	-
62 Samarium	Sm-153	W, all compounds	4E-9	-	-
			-	3E-5	3E-4
38 Strontium	Sr-90	D, all soluble compounds except $SrTiO_3$	-	-	-
			3E-11	5E-7	5E-6
		Y, all insoluble compounds and $SrTiO_3$	6E-12	-	-
43 Technetium	Tc-99m	D, all compounds except those given for W	2E-7	1E-3	1E-2
		W, oxides, hydroxides, halides, and nitrates	3E-7	-	-
81 Thallium	Tl-201	D, all compounds	3E-8	2E-4	2E-3
54 Xenon	Xe-133	Submersion	5E-7	-	-
39 Yttrium	Y-90	W, all compounds except those given for Y	9E-10	-	-
			-	7E-6	7E-5
		Y, oxides and hydroxides	9E-10	-	-

Survey Type	Wipe Surveys Tested over 100 cm^2 Surface		Reference	Comments and Dose Rate Measurements
	Test Frequency	Test Limit		
General Survey	"as appropriate"		120-0180	• 2 mrem in one hour
		• 10 CFR 20 Appdx B limits	120-0190	• Must show compliance with 120-0180
			120-0200	• Evaluate magnitude and extent of radiation levels • Concentrations or quantities • Potential hazards
Medical: Areas of use	Daily (end of day)	33.3 Bq (2000 dpm)	116-0250	• Instrument sensitivity at least 1 Sv/hr (0.1 mrem/hr) • Notify RSO if Action Levels exceeded

- Guidance:
  - NCRP 112
  - ANSI N323A, *Radiation Protection instrumentation Test and Calibration, Portable Survey Instruments*, 1997
  - ANSI N13.27, *Performance Specifications for Pocket-Sized Alarming Dosimeter/Rate Meters*, 1981
  - ANSI N13.5, *Performance Specifications for Direct Reading and Indirect Reading Pocket Dosimeters*, 1989
- Scaler/contamination meter tests and calibrations
- Uptake probes
- Well counters
- Radiopharmaceutical Dose calibrators OAR 333-116-0160(2)
  - Geometry OAR 333-116-0160(2)(d)
    - Prior to first use
    - After each repair
    - If device is moved
  - Daily Constancy OAR 333-116-0160(2)(a)
  - Quarterly Linearity OAR 333-116-0160(2)(c)
  - Annual Accuracy OAR 333-116-0160(2)(b)
- Beta-Emitter Dose calibrators OAR 333-116-0165
  - Annual Accuracy OAR 333-116-0165(b)
  - Annual Linearity OAR 333-116-0165(c)
  - Daily Constancy OAR 333-116-0165(d)
- Brachytherapy dose calibrators
- Portal monitor tests
- Emergency Response Instruments
  - Includes RPS HPP/REP instruments

FE6 Radiation Safety Training and Practices

- Assess training program, implementation and effectiveness
  - Observations, demonstrations, interviews, document review
  - Refer to training requirement table at bottom of this focus element (FE6)
  - Postings, Notices, and posted instructions per Posting Requirements table (FE6)

Training Requirements				
Training Category	**Reference**	**Frequency**	**Target Audience**	**Training Requirements**
Basic	111-0010	3-year refresher	All workers frequenting a Restricted Area	• Storage, transfer or use of radiation • Health Effects, and Protection Measures • Regulations • Report issues to management • Emergency procedures • Personnel Dosimetry program
Tie-Downs	License Conditions	dependent on license	dependent on license	dependent on license
DOT Hazmat	118-0050(1)(a)(F)	w/in 90 days, and 3-year refresher	defined in 49 CFR 171.8 • Impacts transport safety • Handles, loads, or unloads hazmat • Prepares shipments • Responsible for safety • Operates hazmat vehicle	Tied to 49 CFR 172.704 • General awareness of rules • Function specific (rule-based) o Safety Training o Emergency Response o Protective Measures • Procedures o Security awareness o Security risks o Threat recognition • Detailed Security o Security Plan
Supervised RAM use	116-0100	not stated in rule	work under supervision to: • Receive • Possess • Use • Transfer	• Rad protection procedures • WD Procedures • QMP • Regulations appropriate to use • License Conditions appropriate to use • RAM preparation
Radio-pharmaceutical Therapy Workers	116-0370	1-year refresher	Personnel for care for therapy in-patients	Oral and Written: • Patient/subject control • Visitor control and Dose Limits • Contamination control • Waste control • Internal Notification procedures
Brachytherapy Workers	116-0430	1-year refresher	Personnel caring for implant therapy patients	Oral and Written: • All requirements for radiopharm therapy apply • Size and appearance of sources • Emergency handling and shielding
Workers for Afterloader, Teletherapy, Gamma Stereotactic Radiosurgery	116-0495	Initial, and 1-year refresher	Persons who operate the unit (HDR unit, gamma-knife unit, etc.)	Instruction and Posting on Unit: • Emergency procedures • Emergency Access Control • Emergency Contacts • Operating procedures • Conduct Annual Drills for Operators, AMPs, and AUs

FE7 Management Oversight

- Authority
  - Authorizations compliant with OAR 333-116-0090
  - RSO Authority OAR 333-116-0090(6)
    - Identify safety issues
    - Stop unsafe operations
    - Initiate, recommend, and provide corrective action
    - Verify implementation of corrective action
- Organization matches license commitments
- Supervision OAR 333-116-0030(2), 0100, OAR 333-100-0005(137)
  - See training requirements table
  - Defined OAR 333-100-0005(137)
    - Responsibility for control of application, quality, safety, technical aspects
- Program Documented per OAR 333-100-0057
- Radiation Safety Committee (RSC)
  - Required if
    - Two or more Types of RAM use OAR 333-116-0090(7)
    - PET facilities OAR 333-116-0810(3)
  - Review and Approve all program changes OAR 333-116-0123(1)(c)
  - 6-month meeting frequency OAR 333-116-0090(8)
  - Membership OAR 333-116-0090(7)
    - AU for each type of RAM use
    - RSO
    - Nursing
    - Management (not AU or RSO)
  - Broad Scope A 333-116-0055
- Audit Programs (annual)
  - ALARA OAR 333-120-0020(2, 4)
  - Radiation Protection Program
    - Appropriate to program OAR 333-120-0020(1)
    - Review program, and it's implementation OAR 333-120-0020(3)
  - Quality Management Program (QMP) OAR 333-116-0125
    - QMP audit covers:
      - Representative sample of WD administrations
      - All Recordable Events
      - All Misadministrations
    - Inspection Points of QMP audit
      - WD was prepared
      - 2-forms of ID were used
      - Final Plans were in accordance with WD
      - Treatment was consistent with WD
      - Any unintended deviation from WD is ID'd, evaluated, and corrected
  - Incident investigations and corrective actions
- Notifications
- Corrective Actions

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INFORMATIONAL BULLETIN

June 30, 2008

To: Radiation Safety Officer
Medical Therapy Licensees

From: Todd Carpenter, Manager
Radioactive Materials Licensing Program

Subject: Supplemental guidance for patient release after therapeutic administration of Iodine-131

The Nuclear Regulatory Commission's (NRC) regulatory summary 2008-11 titled Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administrations of Iodine-131 was released May 16, 2008. This summary is available by viewing the NRC's public website at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2008/index.html.

The guidance is a supplement to the NUREG 1556, Volume 9, Rev.2, "Program Specific Guidance about Medical Use Licenses" and was issued to inform licensees on precautions that should be taken to protect infants and young children who might be in contact with patients after receiving therapeutic amounts of Iodine-131.

Licensees are advised to consider not releasing patients whose living conditions might result in unnecessary radiation exposure to infants and young children. Guidance specifics may be found in enclosure 1 of the RIS or Appendix U of the NUREG-1556, Vol. 9, Rev 2, "Program Specific Guidance about Medical Use Licenses". No specification or written response is required by this RIS.

If you have any questions please feel free to call our office @ (971) 673-0500.